

Food and Drug Administration Baltimore District Office Central Region 6000 Metro Drive, Suite 101 Baltimore, MD 21215 Telephone: (410) 779-5454 FAX: (410) 779-5707

March 8, 2004

CONSENT DECREE CORRESPONDENCE

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Mr. Alan McCurry
Executive Vice President and CEO
Biomedical Services
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006

RE: United States v. American National Red Cross, Civil Action No. 93-0949 (JGP)

Dear Mr. McCurty:

By letter dated February 6, 2004, FDA informed the American National Red Cross (ARC) that it would be fined \$450,000 for failing to submit a Problem Management standard operating procedure adequate to bring ARC into compliance with the law and the Amended Consent Decree (Decree). ARC's appeal period for the imposition of this fine expired on February 26, 2004. Payment of this fine is due thirty days after the expiration of the appeal period, on March 29, 2004.

In accordance with paragraph IX.F.7. of the Decree, we are attaching instructions for electronic transfer of this payment to the United States Treasury. ARC must, contemporancous with the electronic transfer, provide written notification to the FDA Director, Baltimore District and the Associate Commissioner of Regulatory Affair that payment has been made.

If you have any questions regarding this response, please contact me at (410) 779-5424.

Sincerely yours,

Lee Bowers

Director, Baltimore District

ATTACHMENT

Mr. Alan McCurry Page 2

cc: Marsha Johnson Evans
President & CEO
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006

Mary Elcano General Counsel American National Red Cross 2025 E Street, N.W. Washington, D.C. 20006

David T. McLaughlin Chairman, Board of Governors American National Red Cross 2025 E Street, N.W. Washington, D.C. 20006